



**Hospices
Civils de
Lyon**



Annuloplasties Néocordages : Place actuelle ?



**Cardiothoracic and Vascular Surgery Department
Hôpital Louis Pradel
LYON - France**

<u>Affiliation/Financial Relationship</u>	<u>List of companies</u>
> Grant/Research Support	Boeringher, Abbott, Medtronic, Edwards, Neochord
> Consulting Fees/Honoraria	Edwards, Saint Jude Medical, Medtronic, Servier, Novartis
> Major Stock Shareholder/Equity	
> Royalty Income	Landanger, Delacroix-Chevalier
> Ownership/Founder	
> Intellectual Property Rights	Landanger, Delacroix-Chevalier
> Other Financial Benefit	Sorin, Astra Zeneca



INTRO

Neochord

Indirect Rings

Direct Rings

Conclusion

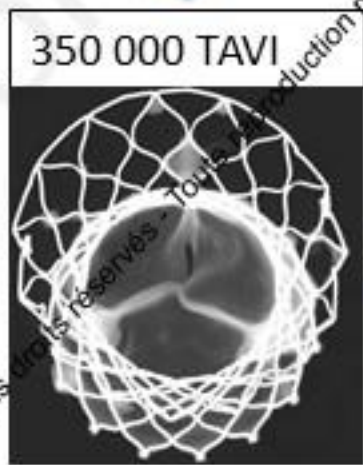
100aines mil...

→ Milliers

→ Centaines

→ Dizaines

→ unités

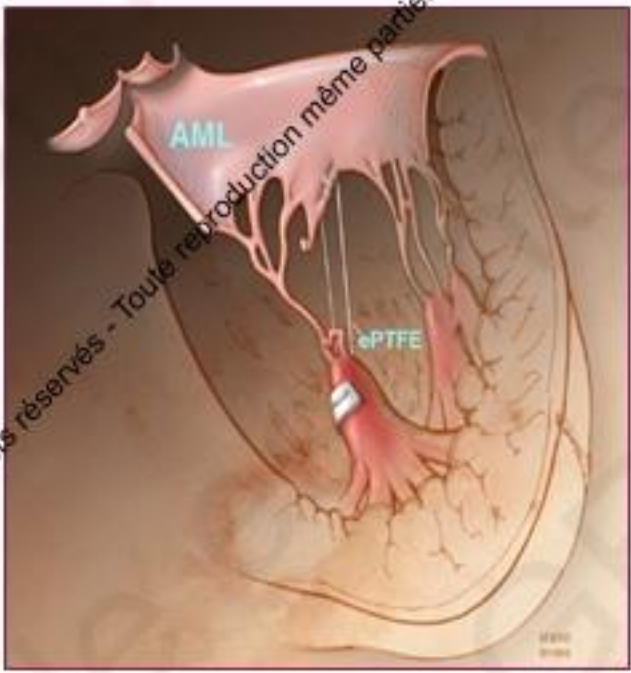


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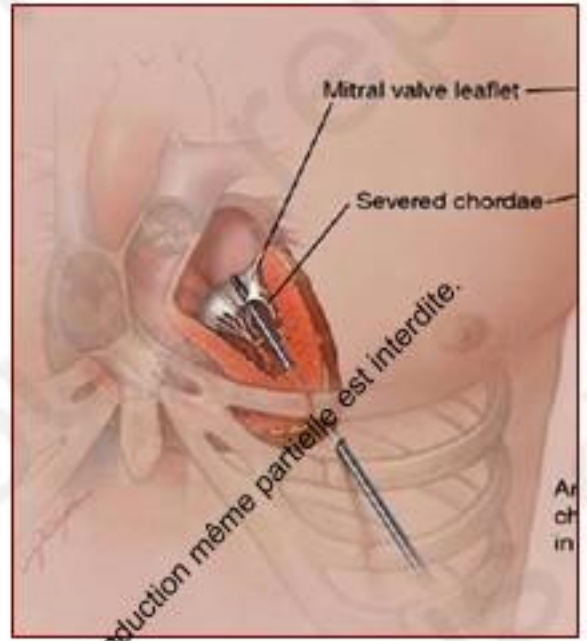


INTRO

Transapical Off Pump MV Repair



- 2009 : 1^{er} patient**
- 2013 : CE mark**
- 2014 : 100 Pts**
- 2015 : 300 Pts**
- 2017 : > 750 Pts**



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Severe P2 prolaps :

- *excess tissue*
- *no annular dilatation*



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INTRO

Neochord

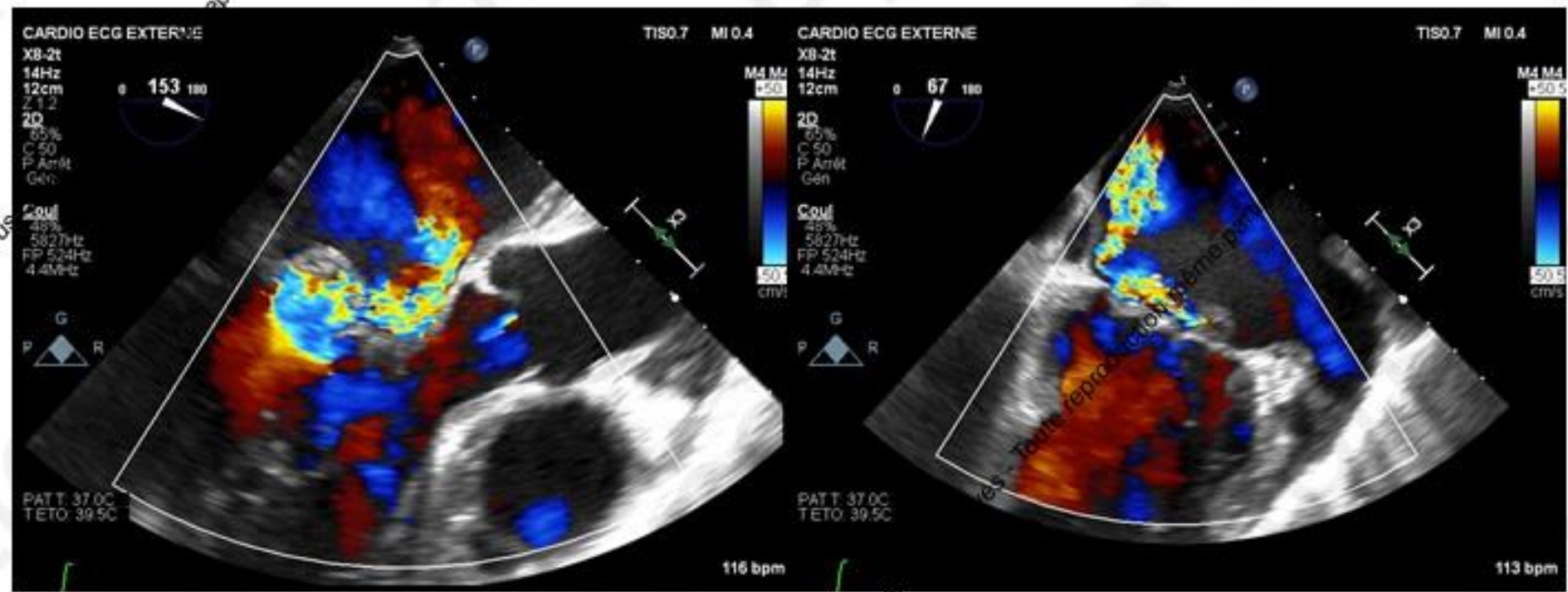
Indirect Rings

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Conclusion

Severe P2 prolaps :

- *excess tissue*
- *no annular dilatation*



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Hôpitaux de Lyon

INTRO

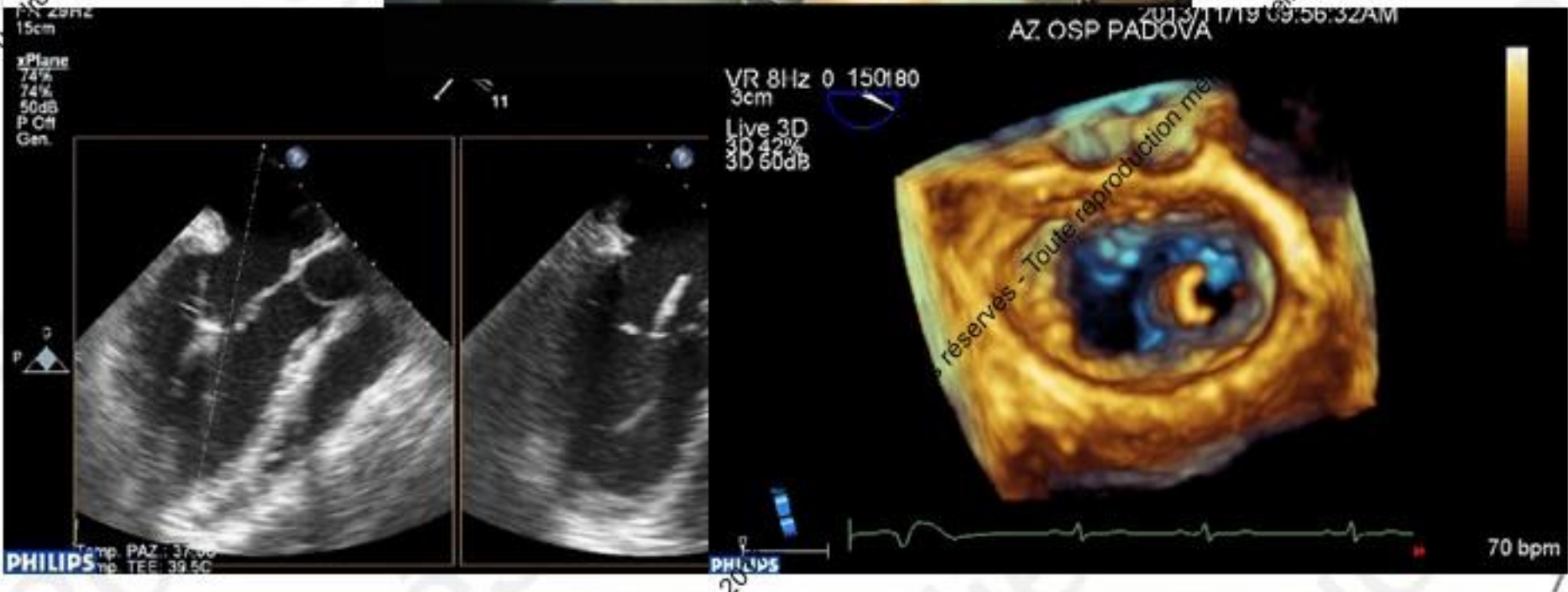
Implantation Technique

Neochord



Indirect Rings

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Direct Rings

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Post-implantation control



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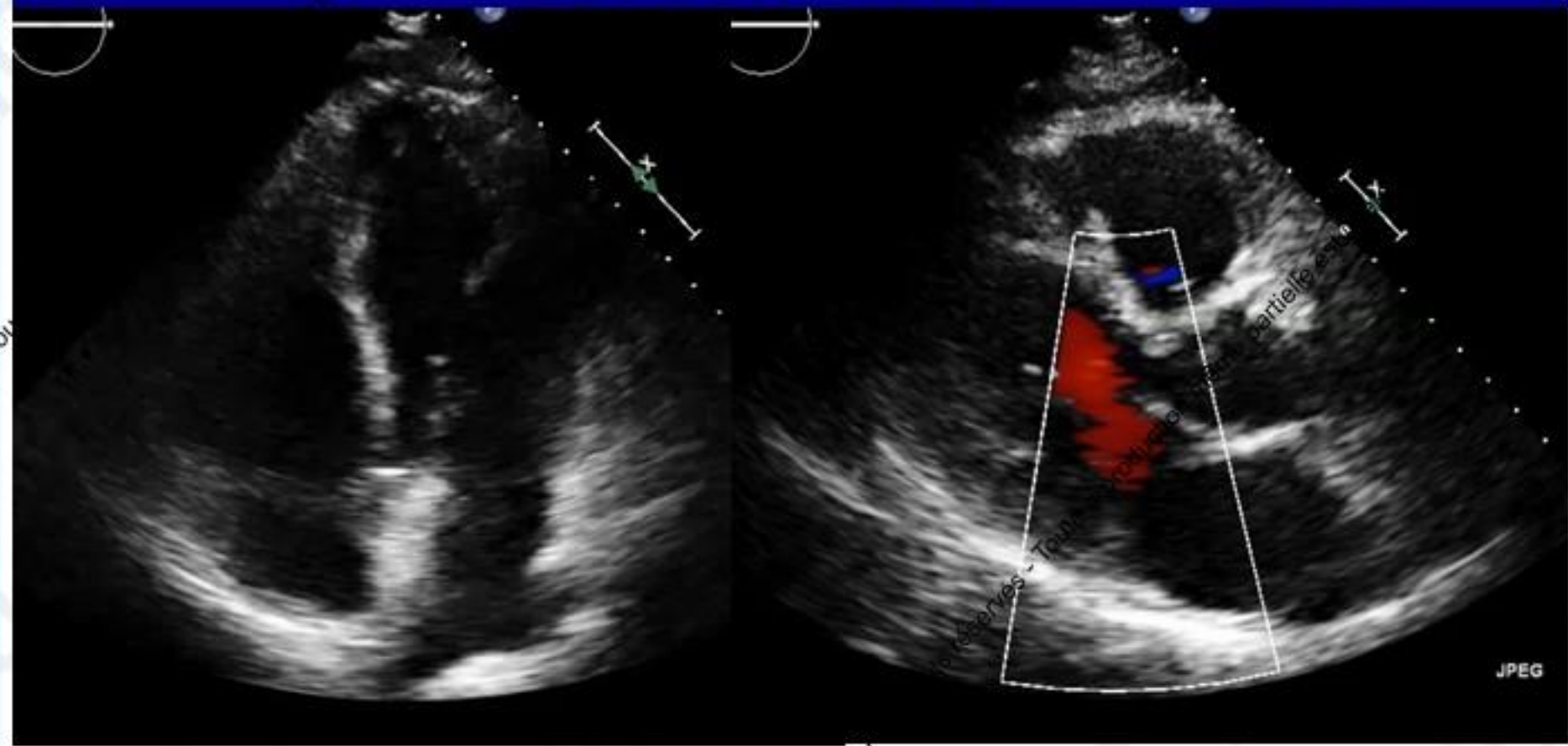
Neochord

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1 Year Follow-up



JPEG

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INTRO

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92 patients	Dr Andrea COLLI – Padua
Age (years)	65 (57-75)
Male	68 (73.9%)
Euroscore-II (%)	1,17 (0,7-1,9)
Previous Cardiac Surgery	3 (3,3%)
- NYHA I	10 (10,9%)
- NYHA II	42 (45,7%)
- NYHA III	39 (42,3%)
- NYHA IV	1 (1,1%)
MR grade	
- Absent/trace	0 (0%)
- Mild	0 (0%)
- Moderate	0 (0%)
- Severe	92 (100%)

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Baseline Characteristics	Median (I-III Quartile) or N (%)
Anatomic MV type	
- A	32 (34,8%)
- B	60 (65,2%)
Left ventricular ejection fraction (%)	
- ≤ 30	62 (58-67)
- 31-55	0 (0%)
- > 55	22 (23,9%)
Left ventricular end diastolic volume (ml/m²)	
- < 70	81,0 (70,9-91,9)
- 70-100	20 (21,7%)
- 100-130	68 (68,4%)
- > 130	9 (9,8%)
Pulmonary artery hypertension (mmHg)	
- ≤ 25	31.5 (26,8-40)
- 26 – 35	21 (22,8%)
- 36 – 45	34 (36,9%)
- > 45	14 (15,2%)
	19 (20,7%)



INTRO

Neochord

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Operative Characteristics	Median (I-III Quartile) or N (%)
Neochordae in place (n)	4 (3-4)
2	3 (3,2%)
3	26 (28,3%)
4	45 (48,9%)
5	13 (14,1%)
6	4 (4,3%)
7	1 (1,1%)
Conversion to conventional surgery	1 (1,1%)
Procedural ECMO support	2 (2,2%)
Procedural IABP support	1 (1,1%)
Access site complications	0 (0,0%)
Ventricular fibrillation	1 (1,1%)
Operative time (min)	130 (116-155)

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Postop. course

	Median (I-III Quartile) or N (%)
Mechanical ventilation time (hours)	2 (0-3)
- 0 (OR extubation)	24 (23.4%)
- ≤ 3	52 (57,1%)
- 4-6	7 (7,7%)
- > 6	8 (8,8%)
Hospital stay (days)	7 (6-8)
Discharge	
- Home	64 (70,3%)
- Rehabilitation center	26 (28,6%)
- In hospital death	1 (1,1%)
Procedure success	91 (98,9%)
Transient ischemic attack	1 (1,9%)
Stroke	0 (0.0%)

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MR Overall

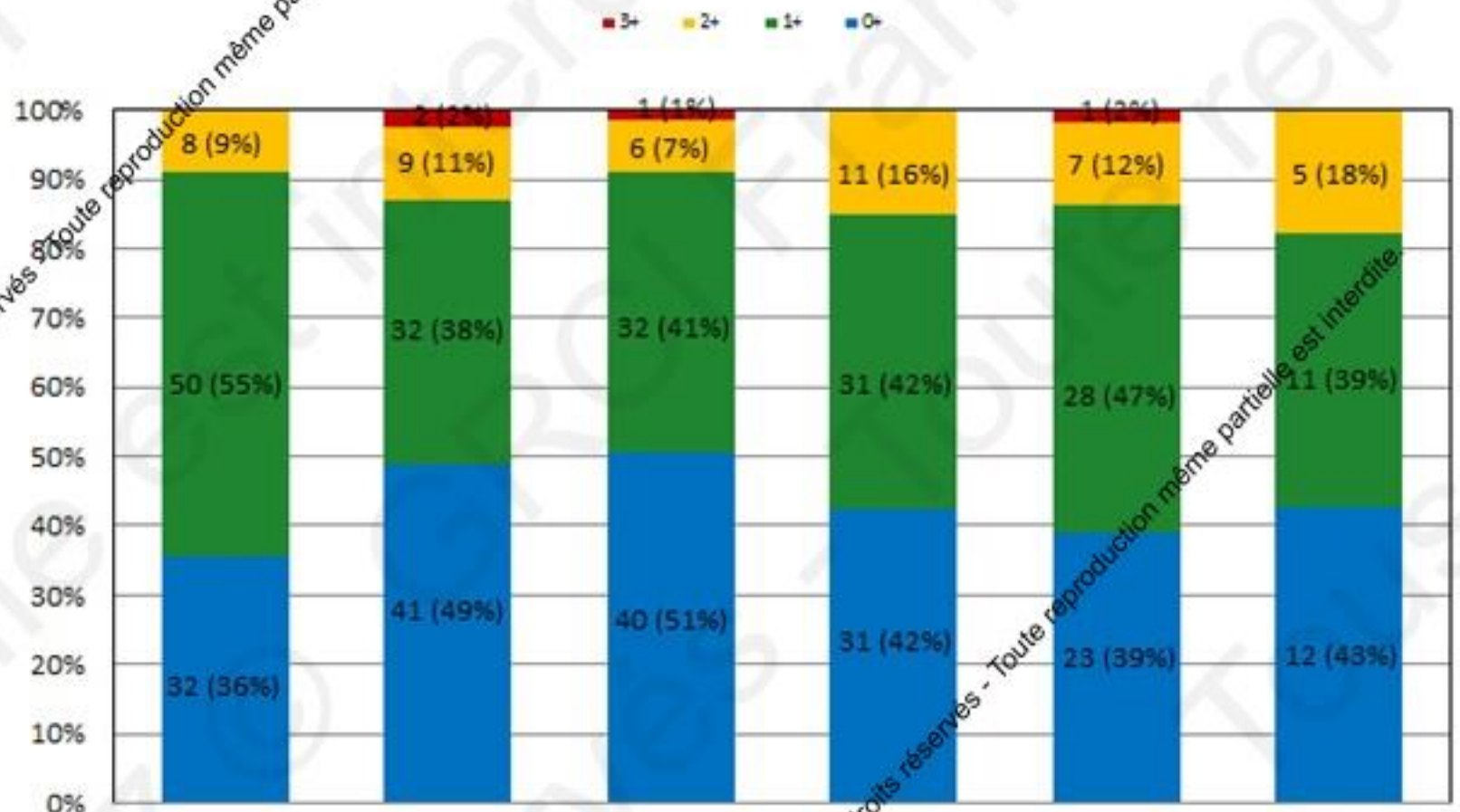
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Pts at risk

90 84 79 73 59 28

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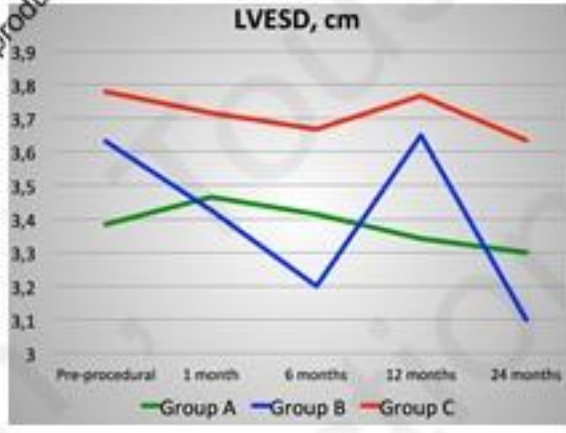
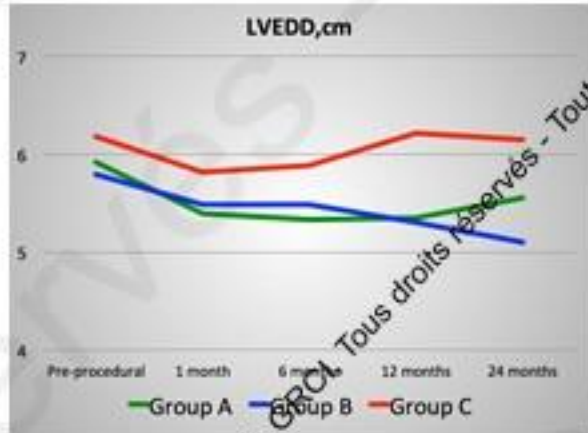
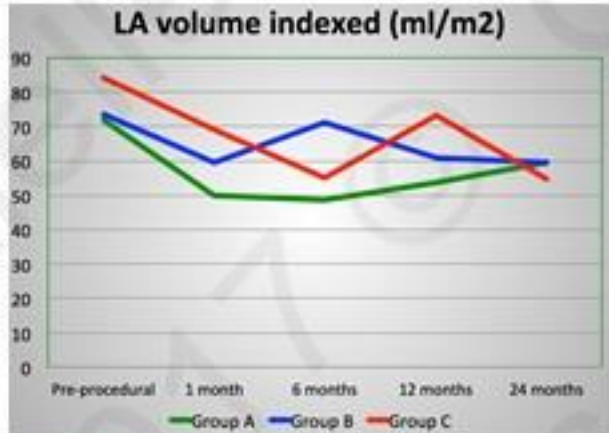
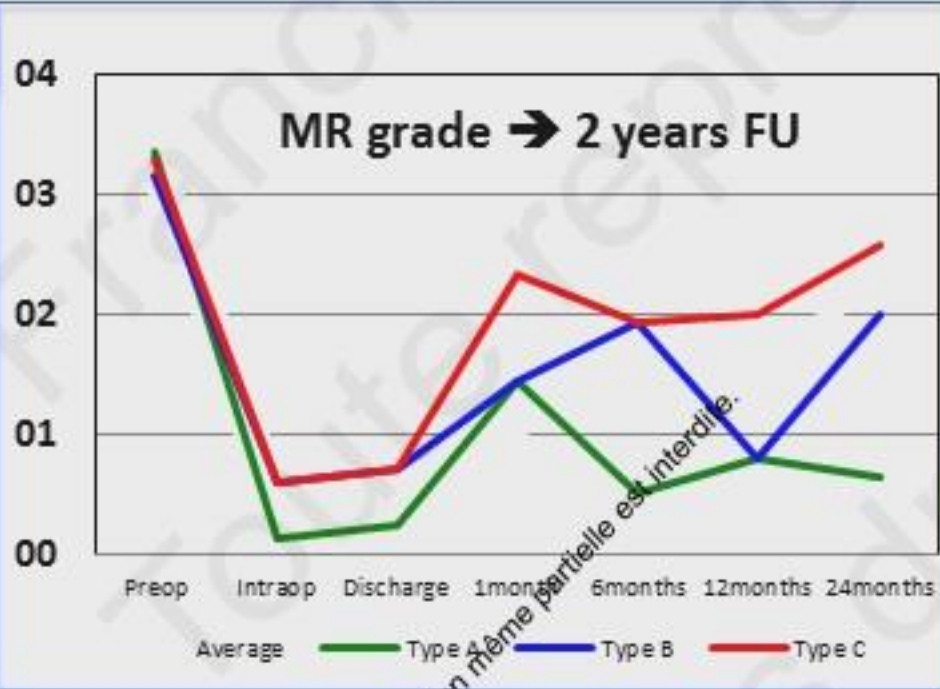
Neochord

Indirect Rings

Direct Rings

Conclusion

Type A	Type B	Type C
<ul style="list-style-type: none"> Eccentric regurgitant jet Central P2 prolapse, extension up to 50% of entire PML. No pericommissural involvement No anterior leaflet prolapse or tethering No severe LV dilatation 	<ul style="list-style-type: none"> Eccentric regurgitant jet Extension of prolapse to include the portions of P1 or P3 adjacent to P2 Or may have more than one prolapsing segment (P1+P2, P2+P3) 	<ul style="list-style-type: none"> Prolapse extending towards the commissures, involvement of anterior leaflet LV dilatation with initial tethering of AL (gullwing sign) Central component to regurgitant jet (lack of central coaptation) Calcified leaflet segments

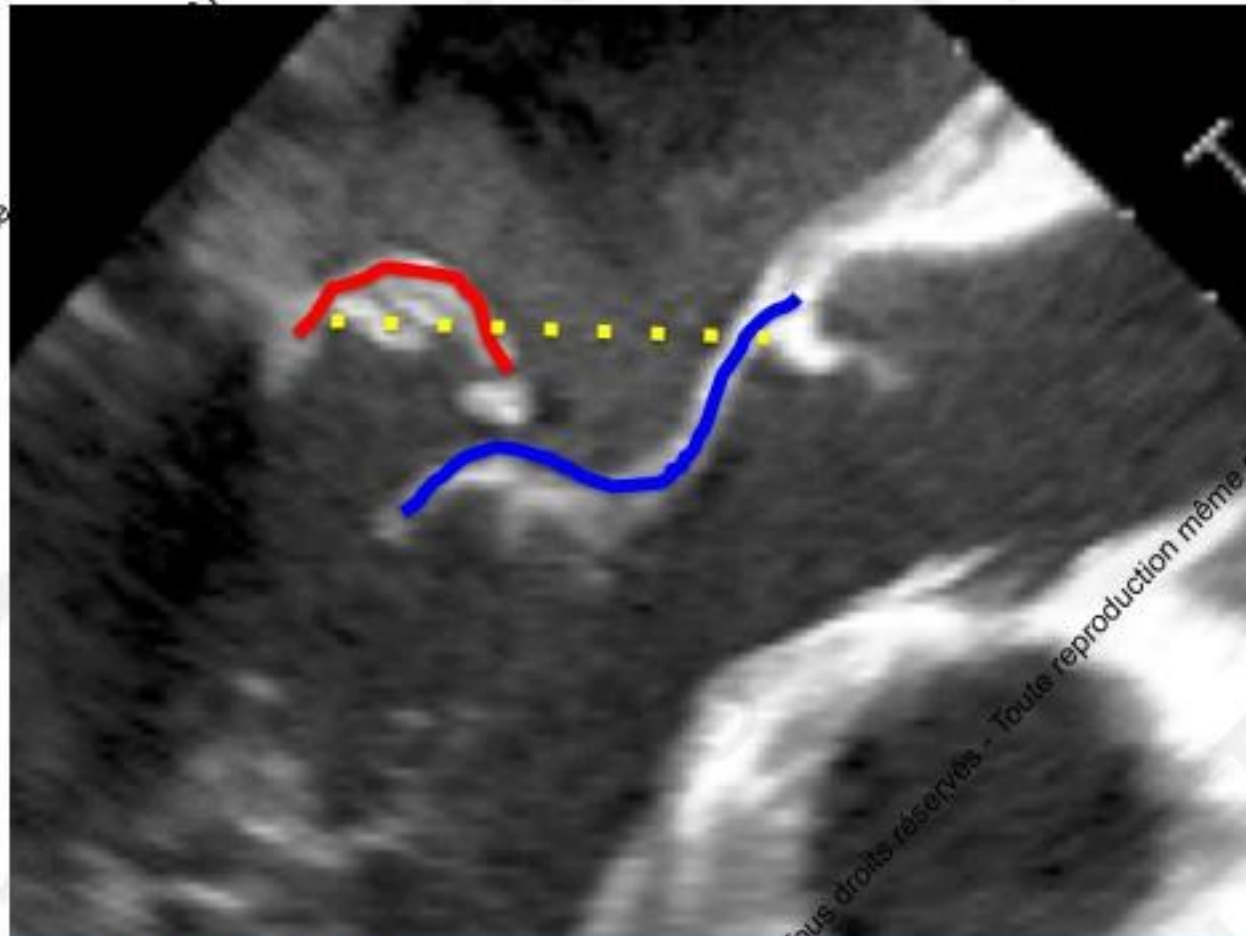


Vilniaus universiteto ligoninės
SANTARIŠKIŲ KLINIKOS

2 years Vilnius Experience, K. Rucinskas Vilnius, Lithuania



Leaflet to Annulus Index > AP distance



$$\frac{\text{PML} + \text{AML}}{\text{AP}} > 1.25 \text{ predictive of success}$$

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INTRO

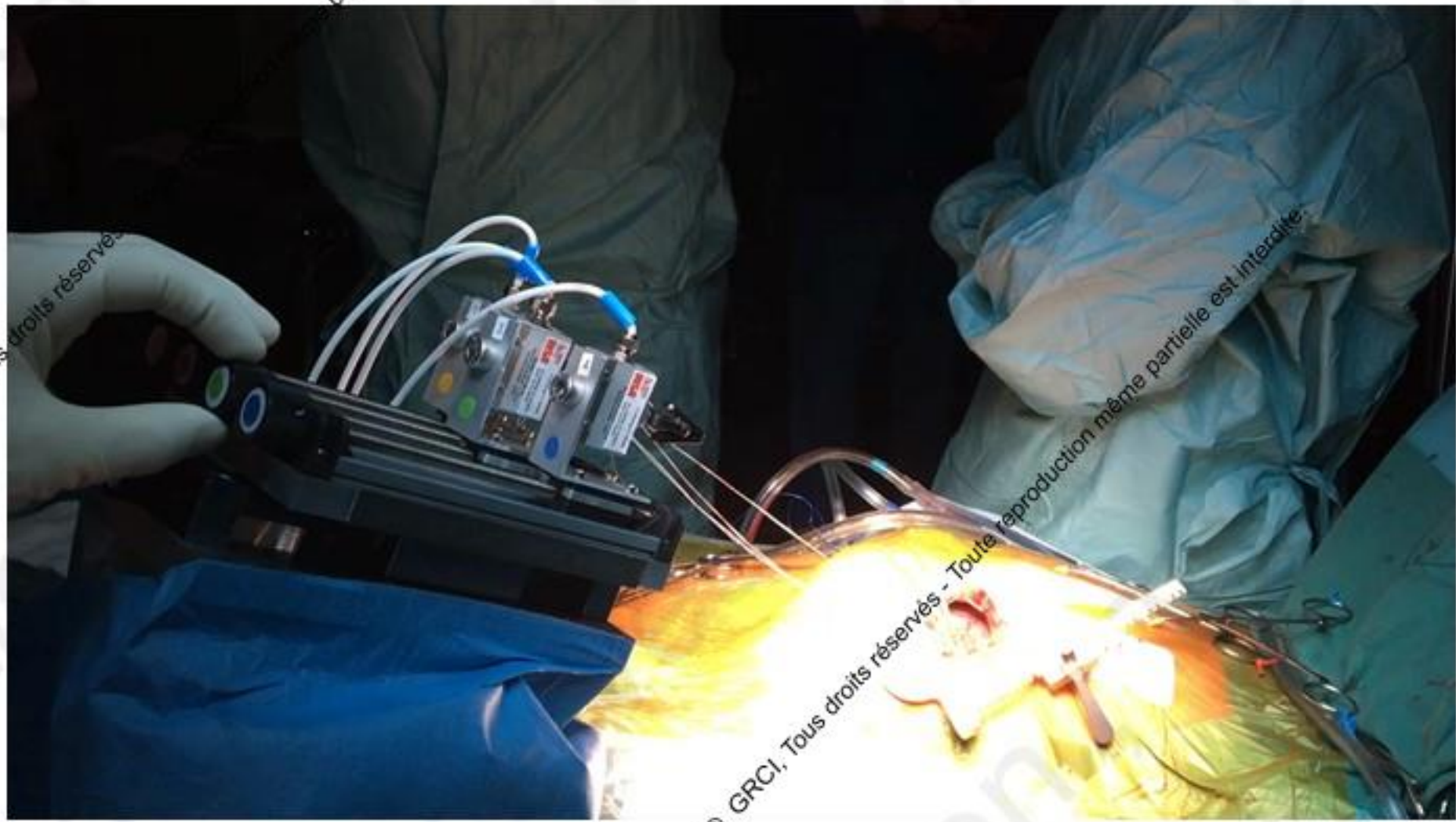
What are the forces ? Which Tension is most suitable ?

Neochord

Indirect Rings

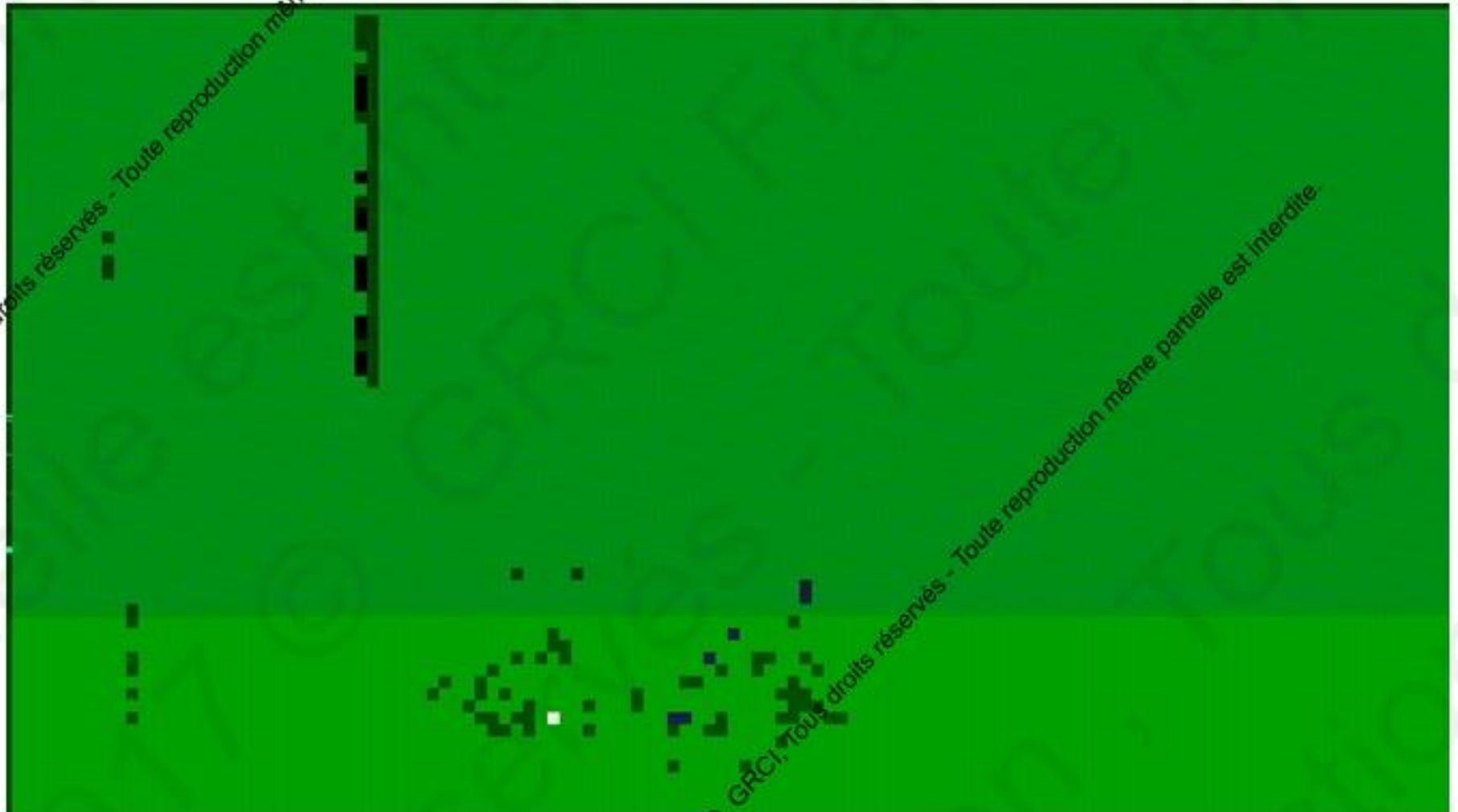
Direct Rings

Conclusion





What are the forces ? Which Tension is most suitable ?





INTRO

Neochord

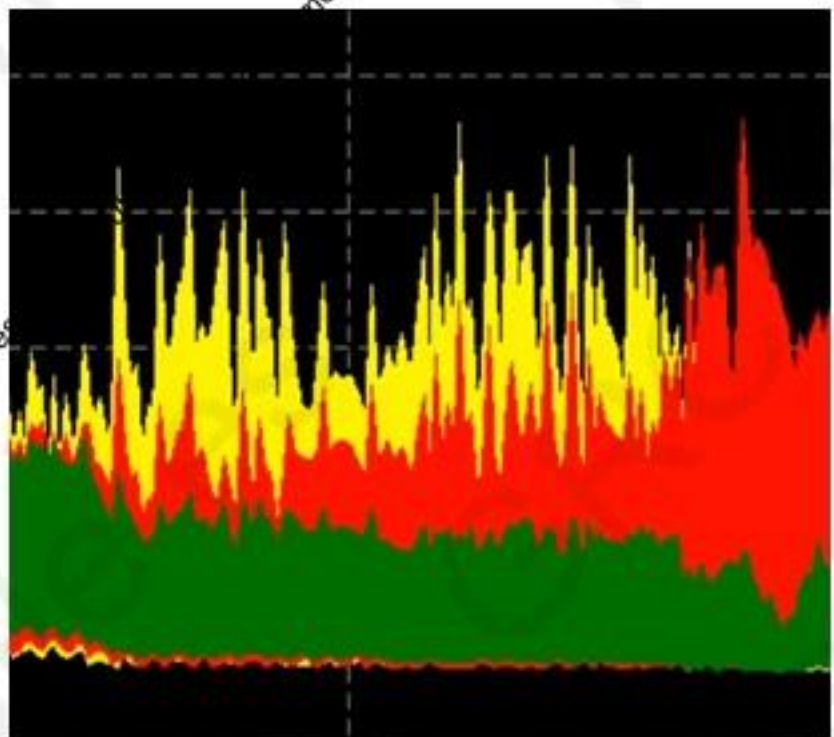
Indirect Rings

Direct Rings

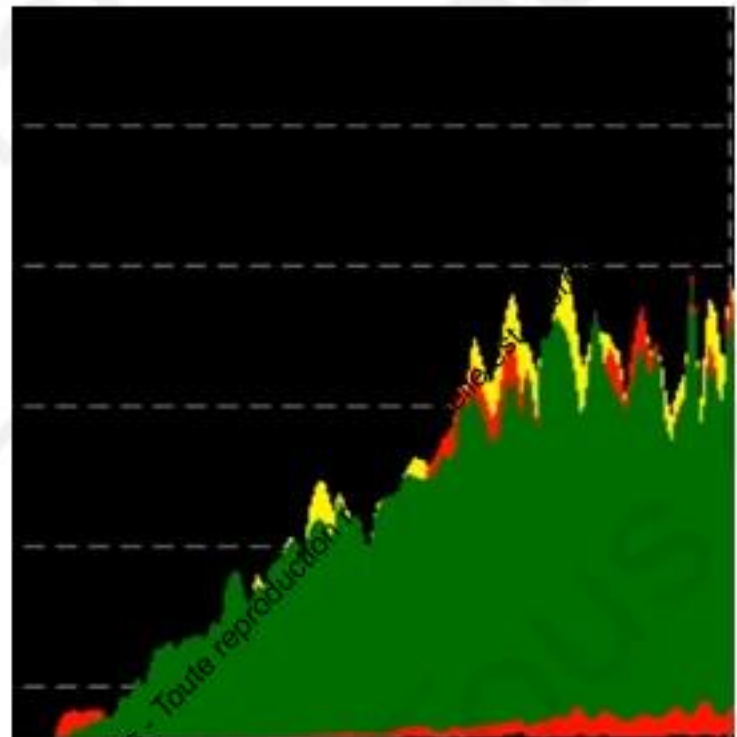
Conclusion

Manual Assessment

Assessed Control



AI 1/PEAK-PEAK [N]	AI 2/PEAK-PEAK [N]	AI 3/PEAK-PEAK [N]
1.24	0.84	0.32
Sensor 1	Sensor 2	Sensor 3



AI 1/PEAK-PEAK [N]	AI 2/PEAK-PEAK [N]	AI 3/PEAK-PEAK [N]
0.64	0.50	0.45
Sensor 1	Sensor 2	Sensor 3

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Conclusion

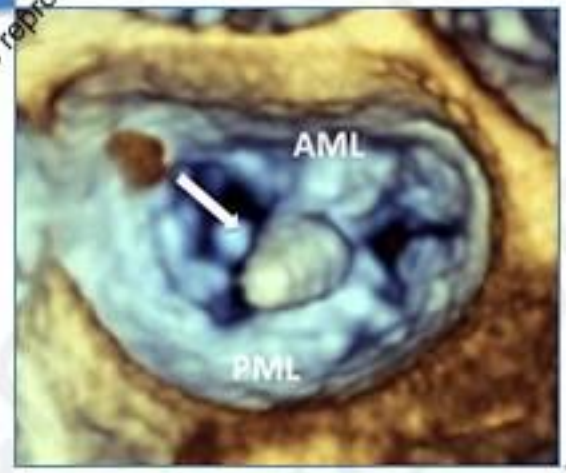
Quelle place pour Neochord ?

Mitrachord Criteria:

- Any Symptomatic
- **P2 or A2 Prolapse**
- LVEF > 30%

PML + AML
AP

>1.25 predictive of MR$\leq 1+$ at 1y FU



Tout est inutile
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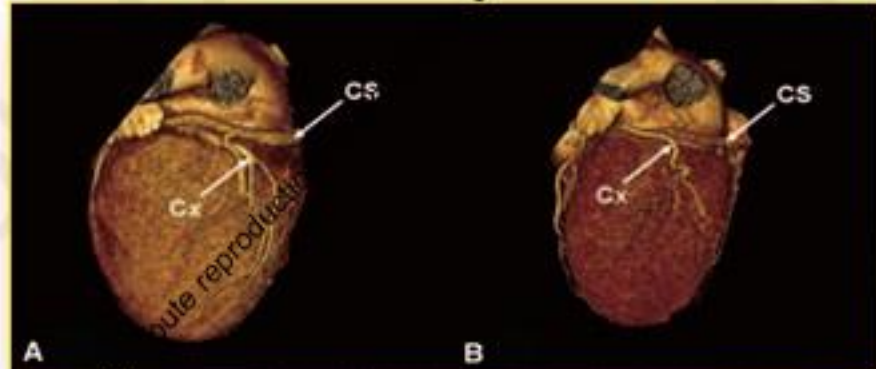
INDIRECTE Annuloplasty

	<p>MONARC (Edwards Lifesciences LLC)</p>	<p>Two-anchor design with chronic reshaping (6 weeks) by a foreshortening bridge</p>	<p>EVOLUTION trial (72 pts 82% success)</p>
	<p>CARILLON (Cardiac Dimensions Inc)</p>	<p>Acute reshaping device acting in P2P3, repositionable, retrievable</p>	<p>AMADEUS trial (113 pts 58% success)</p>
	<p>PTMA (Viacor Inc)</p>	<p>Tri-lumen catheter, reshapable, possibility of multiple long term adjustment</p>	<p>PTOLEMY (31 pts 29% success)</p>

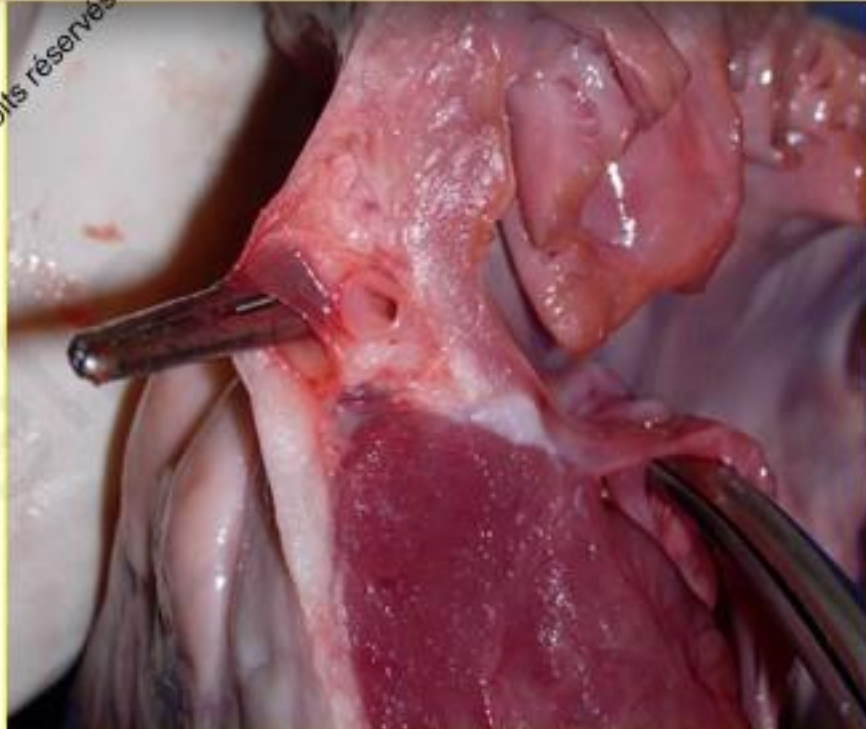


INTRO

Neochord

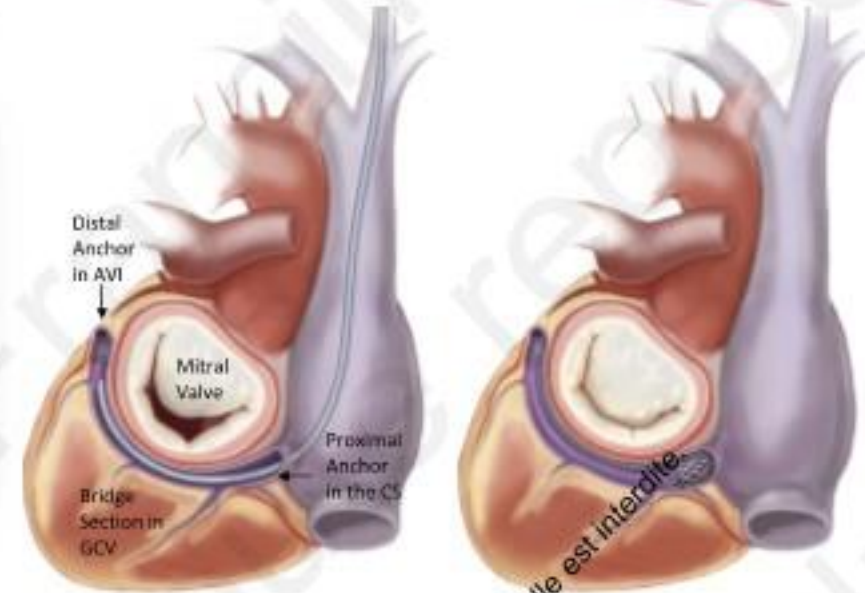


Indirect Rings

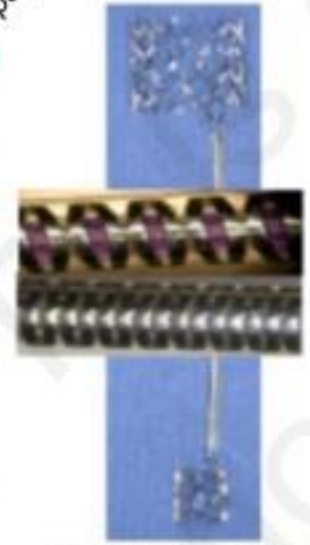


Direct Rings

Conclusion



The MONARC system
Delayed Release-in-situ



Webster of Circulation 117:833-835, 2006

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INTRO

Valtech Cardio – CARDIOBAND

First in man in 2013



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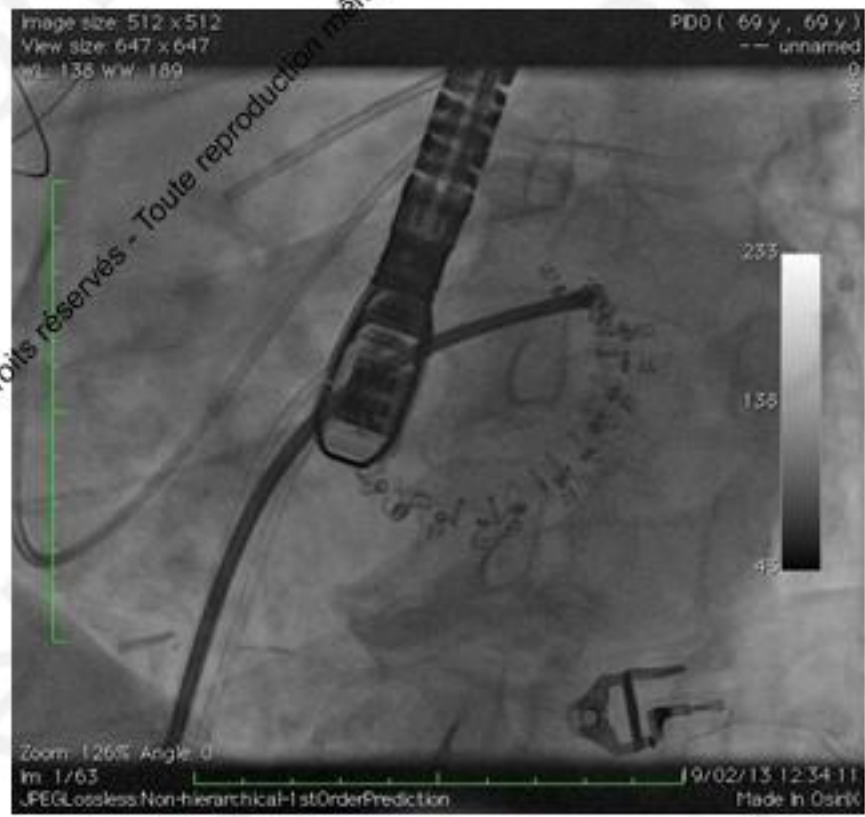
Valtech Cardio – CARDIOBAND

Neochord

Indirect Rings

Direct Rings

Conclusion





INTRO

Cardioband European Study Early Outcomes (N=30)

Courtesy of Francesco MAISANO

Neochord

Indirect Rings

Direct Rings

Conclusion

Procedure

- Implants successfully deployed on annulus (30/30)
- Average reduction of septolateral diameter 20%

Effectiveness

- MR \leq 2+ in 1 month follow up (N=27) 89%
- MR \leq 2+ in 6 month follow up (N=16) **88%**

Safety

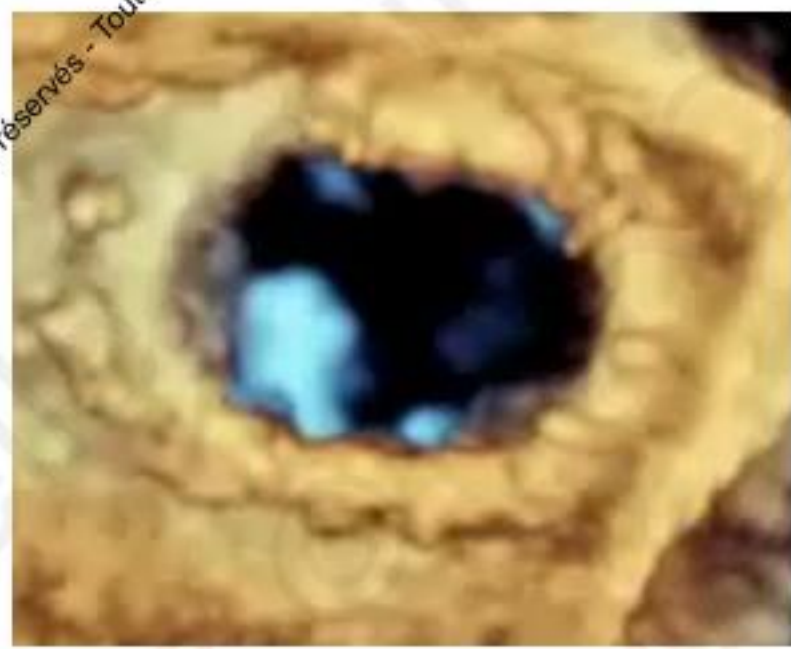
- Procedural mortality 0/30
- 30 days Mortality (according to VARC) 2/30

No Device Related Major Adverse Events as adjudicated by independent committee

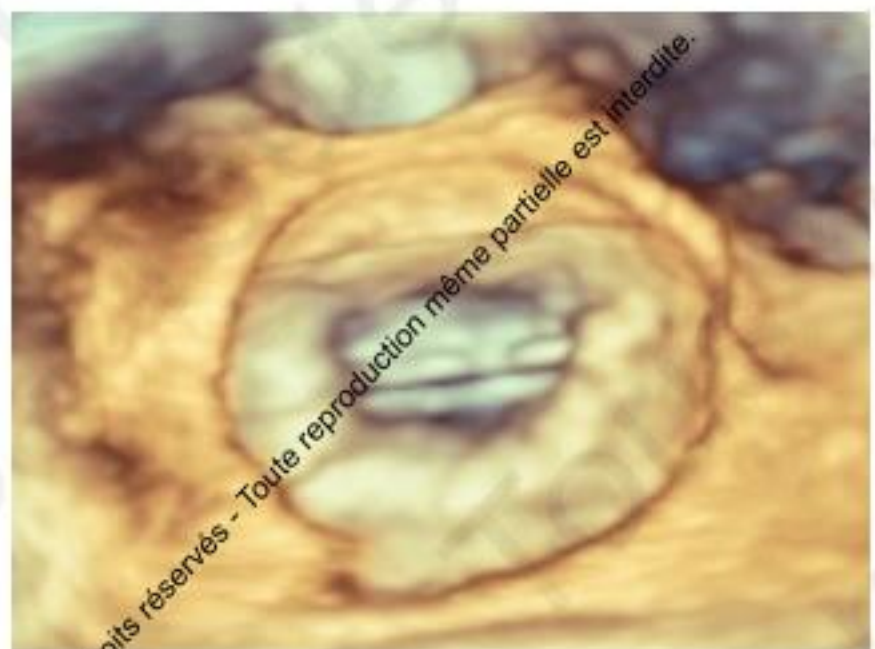
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Which is surgical ? Percutaneous ?



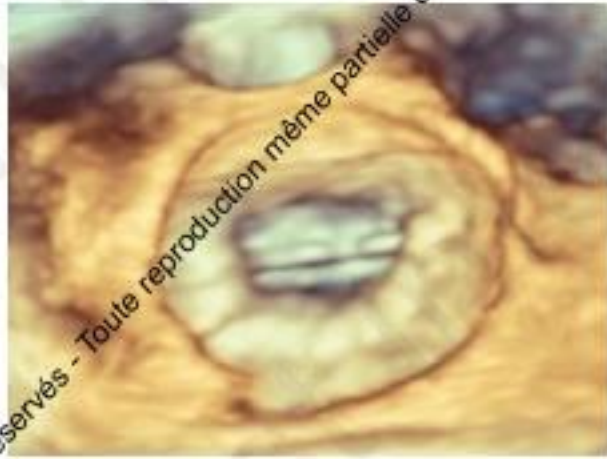
Surgical Ring



Cardioband



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Prospective randomized Study



Edwards Cardioband System ACTIVE Pivotal Clinical Trial
PROTOCOL NUMBER: 2017-05 Rev D

Title	Annular Redu<u>C</u>tion for Transcatheter Treatment of Insufficient Mitral Valve (ACTIVE): A prospective multicenter, randomized, controlled pivotal trial to assess transcatheter mitral valve repair with Edwards Cardioband System and guideline directed medical therapy (GDMT) compared to GDMT alone in patients with functional mitral regurgitation (FMR) and heart failure. (Protocol Number: 2017-05).
Short Title	Edwards Cardioband System ACTIVE Pivotal Clinical Trial



INTRO

Valcare company → Amend Annuloplasty

Neochord

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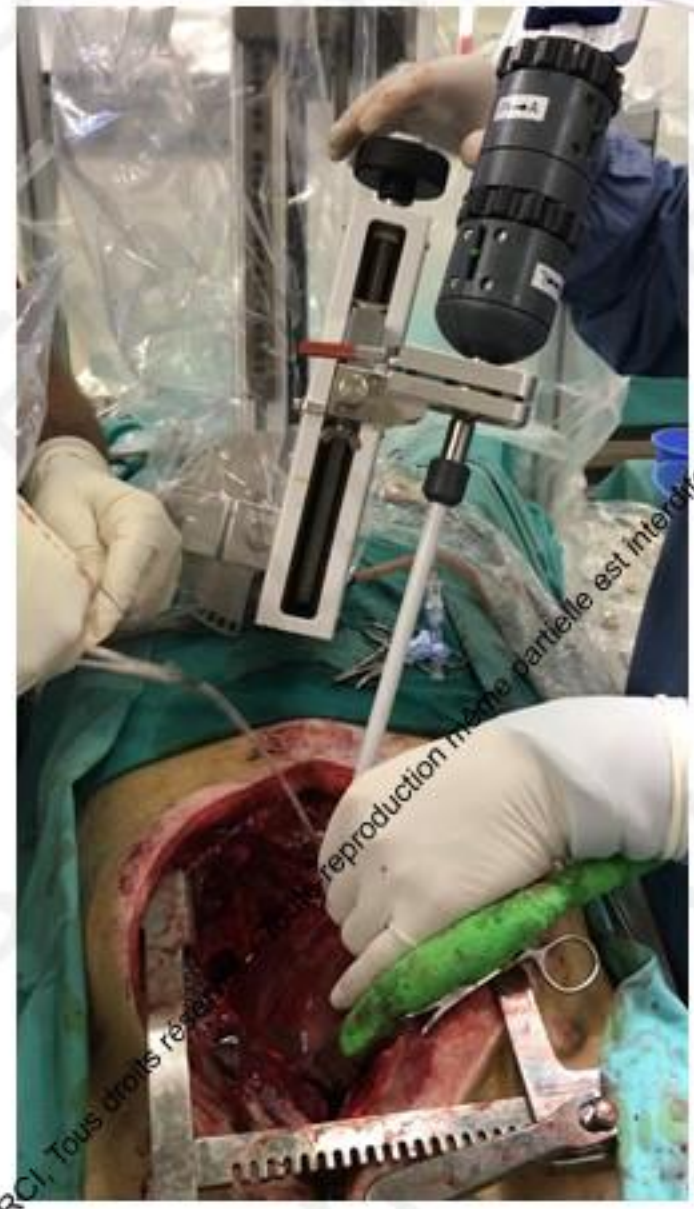
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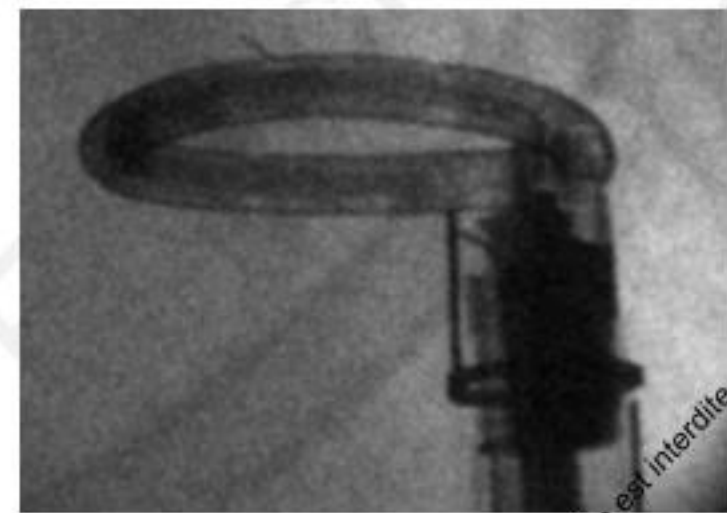
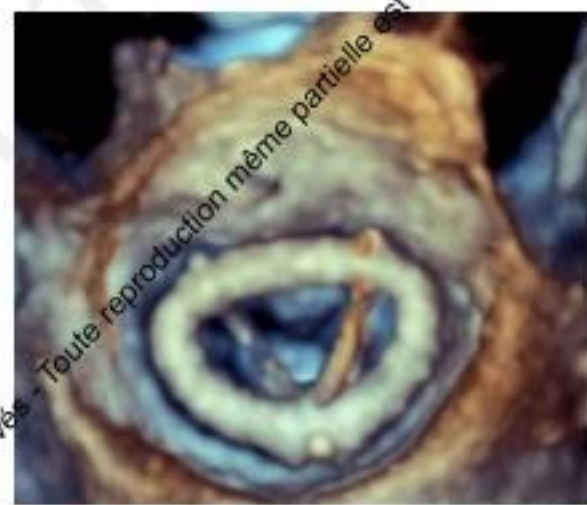
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AMEND™ Size Selection Based on Patient's Morphology

Patient's Commissure to Commissure (mm)		Patient's Anterior-posterior (mm)	AMEND™ Model
29-36	AND	31-36	TAP34
33-40	AND	34-40	TAP37
38-46	AND	38-46	TAP40

Table 3: AMEND™ Annuloplasty Ring size (model) selection



INTRO

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Ring as a docking zone

Combine AMEND™ percutaneous annuloplasty ring with proprietary D-Shape Corona™ Valve



AMEND emulates the current "Gold Standard" for surgical mitral repair

- Closed
- D-shaped
- Semi rigid
- Septal lateral reduction

Corona

- D-shape frame
- 4 leaflet
- 21Fr delivery

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Conclusion

evidence based

Success story



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Prospective French Studies



PHRC 2015 *Mitrachord Primary MR / surg*

2017 2018 2019 2020

PHRC 2014 *Mitra.fr (Secondary MR)*

2015 2016
2017 2018

ESC Aout 2018



PHRC 2016 *Primary MR High risk*

2018 2019 2020 2021....



Reimbursement Primary MR
Contraindication to Surgery